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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,088	08/24/1999	ERNEST G. HOPE	030673	4793

52323 7590 04/10/2006

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/382,088	Applicant(s) HOPE ET AL.	
	Examiner G. R. Ewoldt, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/30/04, 10/05/04, and 12/05/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51 and 60-292 is/are pending in the application.
4a) Of the above claim(s) 80-292 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51 and 60-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election of the species SEQ ID NO:6, without traverse, in the paper filed 12/05/05, is acknowledged. Applicant's amendments and remarks filed 6/30/04 and 10/05/04 are also acknowledged.

2. Claims 80-292 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

3. Claims 51 and 60-79 read on the elected species and are under examination. Note: the claims are under examination only as they read on the polypeptide of SEQ ID NO:6.

4. In view of the instant amendments, the previous rejections under the second paragraph of 35 U.S.C 112 have been withdrawn. Additionally, the previous rejections under the first paragraph of 35 U.S.C 112 for inadequate written description for the introduction of new matter into the claims have also been withdrawn.

5. Applicant's amendments to the figures and specification have been reviewed and have been found acceptable.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 60-79 stand/are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record first set forth in the paper mailed 7/17/01. Specifically, the specification is not enabled for the claimed method employing any of the polypeptides other than those of SEQ ID NOS:3 and 6.

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Applicant's arguments, filed 6/30/04, have been fully considered but they are not persuasive. Applicant argues that the instant case involves "predictable factors" and cites BLAST searching. Applicant cites Figures 2, 9, 11-13, 15, and pages 27, 55, and 68 in support.

Applicant is advised that the argument regarding "predictable factors" might be more persuasive if reference was made to where those factors are specifically disclosed and discussed in the instant specification. Regarding BLAST searching, identifying polypeptides with the requisite percent identity is not the issue, it is demonstrating that a representative number of said peptides, commensurate in scope with the breadth of the claimed method, actually function in the claimed method. Figures 2, 9, 11-13, 15, and pages 27, 55, and 68 merely employ the polypeptides of SEQ ID NOS:3 and 6. Two species, one of which is a fragment of the other, cannot be considered to be representative of the countless species of specific peptides, and even more variants, encompassed by the claims.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 51 and 60-79 stand/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hoppe et al. (1995, IDS).

As set forth previously, Hoppe et al. teaches a method for reducing immune-mediated damage to cells, tissues or organs comprising contacting a cell, tissue or organ with an immunoprotective amount of polypeptide comprising Hsp47 which comprises the amino acid sequence AVLSAEQLR (SEQ ID NO:3), or SEQ ID NO:6, which encompasses the claimed variants thereof and a sequence which hybridizes with a nucleic acid sequence of SEQ ID NO:4, wherein the immune-mediated damage is caused by CIK cells (see particularly the last line of the abstract).

Applicant's arguments, filed 6/30/04, have been fully considered but they are not persuasive. Applicant argues that the reference does not teach a particular amino acid sequence nor does it teach damage by lymphocytes, NK cells, nor NK-like cells.

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It is noted that Applicant has not argued that the Hsp47 of the reference is not the Hsp47 of the instant claims. As a protein's amino acid sequence is an inherent property, as is its biological activity, the protein of the reference inherently comprises its amino acid sequence and inherently provides the protection of the method of the instant claims.

10. The following are new grounds of rejection necessitated by Applicant's amendment.

11. Claims 70-72 and 74-77 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "a polypeptide encoded by a nucleic acid sequence at least 80% identical to a nucleic acid sequence encoding SEQ ID NO:6" (Claim 70).

B) "... a sequence greater than 90% identical to SEQ ID NO:6" (Claim 71).

C) "... a sequence greater than 95% identical to SEQ ID NO:6" (Claim 72).

D) "... a sequence at least 55.5% identical to SEQ ID NO:3" (Claim 74).

E) "... a sequence at least 66.6% identical to SEQ ID NO:3" (Claim 75).

F) "... a sequence at least 77.7% identical to SEQ ID NO:3" (Claim 76).

G) "... a sequence at least 88.8% identical to SEQ ID NO:3" (Claim 77).

Applicant cites no support for the amendments to Claims 70-72. Applicant's remarks, filed 6/30/04, cite support for Claim 74-77 in Figure 2.

Applicant is advised that Figure 2 cannot support the alteration of any and all positions including those that are held constant in the Figure as would be encompassed by the

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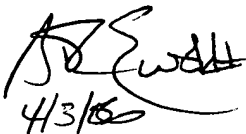
sequences of the claims as now amended.

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

15. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see www.uspto.gov/ebc/newusers.html. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



4/3/16

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Primary Examiner
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